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I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 11-18-04 Signature: Maura A. Gallagher  
(Maura A. Gallagher)

Docket No.: MIY-P02-024  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Chu et al.

Application No.: 10/642397

Confirmation No.: 9981

Filed: August 14, 2003

Art Unit: 3731

For: SYSTEMS, METHODS AND DEVICES  
RELATING TO DELIVERY OF MEDICAL  
IMPLANTS

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of the non US references listed on the PTO/SB/08 is attached. A summary/abstract translation of the non-English language references is enclosed where applicable.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this

Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Applicants call the Examiner's attention to office actions which may have issued in the following co-pending, co-owned patent applications of which subject matters are related to that of the instant application:

<b>U.S. Patent Application Serial Number</b>	<b>Filing Date</b>
10/093,371	March 7, 2002
10/093,398	March 7, 2002
10/093,424	March 7, 2002
10/093,450	March 7, 2002
10/093,498	March 7, 2002
10/094,354	March 7, 2002
10/642,395	August 14, 2003
10/642,365	August 14, 2003
10/641,487	August 14, 2003

Applicant(s) have become aware of the following documents: U.S. Patent No. 6,312,448; U.S. Patent No. 5,904,692; WO 00/74594; EP 1159920; and U.S. Patent No.

5,899,909, cited in an International Search Report issued August 20, 2004, during the prosecution of international application no. PCT/US03/25568, which corresponds to the above referenced application, and in accordance with 37 CFR 1.97(c) and (e)(1) or (b)(3), hereby submit(s) these documents for the Examiner's consideration. These documents are cited on the enclosed PTO Form SB/08, and a copy of the International Search Report and each document cited thereon are enclosed as well.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant(s) understand(s) the Examiner will make an independent evaluation of the cited documents.

The undersigned hereby certifies that each item contained in this Information Disclosure Statement was cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. MIY-P02-024.

Dated: November 18, 2004

Respectfully submitted,

By   
Weishi Li  
Registration No.: 53,217  
ROPES & GRAY LLP  
One International Place  
Boston, Massachusetts 02110-2624  
(617) 951-7000  
(617) 951-7050 (Fax)  
Attorneys/Agents For Applicant



PTO/SB/08a/b (08-03)  
 Approved for use through 07/31/2006. OMB 0651-0031  
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
 Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
				Application Number	10/642397
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	7	Attorney Docket Number	MIY-P02-024

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)	MM-DD-YYYY		
A1	D466213 S		11/26/02	Snitkin et al.	
A2	2,738,790		3/20/56	Todt Sr., et al.	
A3	2,751,903		6/26/56	Ivory et al.	
A4	2,917,878		12/22/59	Edwin et al.	
A5	3,472,232		10/14/69	Earl et al.	
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A9	3,710,795		1/16/73	Higuchi et al.	
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A11	3,875,937		4/8/75	Schmitt et al.	
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A13	3,937,223		2/10/76	Roth	
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A20	4,535,768		8/20/85	Hourahane et al.	
A21	4,592,339		6/3/86	Kuzmak et al.	
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A23	4,739,751		4/26/88	Sapega et al.	
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Examiner Signature	Date Considered
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Sheet	2	of	7	Attorney Docket Number	MIY-P02-024

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Examiner Signature		Date Considered	
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A98	5,813,408	9/29/98	Benderev et al.
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A188	2004/0015048	1/22/04	Neisz et al.	

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY		
	B1	DE 2,305,815 A1	8/8/74		
	B2	DE 2,532,242 A1	2/10/77		

Examiner Signature	Date Considered
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Sheet	5	of	7	Attorney Docket Number	MIY-P02-024

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B5	EP 0 506 920 B1	4/9/97	Salama		
B6	EP 0 628 288 B1	4/5/00	Vidamed, Inc.		
B7	EP 0 831 751 B1	11/6/02	Bogojavlensky et al.		
B8	EP 1 159 920 A2	12/5/01	United States Surgical Corp.		
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B14	FR 1,539,593	9/13/68	Johnson		
B15	FR 2,739,016	3/28/97	Comte Georges		
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B19	SU 1,225,547	4/23/86	N.V. Sklifosovskii Moscow Scientific Research Institute of First Aid		
B20	SU 1,443,873 A1	7/26/89	Kiev State Institute for Further Education of Physicians		
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B24	WO 96/01597	1/25/96	Dacomed Corporation		
B25	WO 96/34587	11/7/96	Uramed Corporation		
B26	WO 96/39227	12/12/96	Urology Inc.		
B27	WO 97/13465	4/17/97	Medscand Medical		
B28	WO 98/12971	4/2/98	Medworks Corporation		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	C1	Bayer et al., "A New Approach To Primary Strengthening Of Colostomy With Marlex Mesh To Prevent Paracolostomy Hernia," <i>Surgery, Gynecology &amp; Obstetrics</i> , 163:579-580, (1986).			
	C2	Benderev, "A New Endoscopic Bladder Neck Suspension For The Outpatient Treatment Of Stress Urinary Incontinence," <i>J. Urology</i> , 149:197a (1993).			
	C3	Benderev, "Anchor Fixation And Other Modifications Of Endoscopic Bladder Neck Suspension," <i>Urology</i> , 40:409-418 (1992).			
	C4	Benderev, Theodore, "A Modified Percutaneous Outpatient Bladder Neck Suspension			
Examiner Signature				Date Considered	

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C5	Delorme, "La Bandelette Trans-Obturatrice: Un Procede Mini-Invasif Pour Traiter l'incontinence Urinaire D'effort De La Femme," Progres En Urologie, 11:1306-1313, (2001) (English Translation Provided).				
C6	Giesy et al., "Ureteral Instrumentation: A New System For Continued Access Via a Safety Guidewire," J. Urology, No. 4, Part 2, P.282a (1988).				
C7	Gittes et al., "No-Incision Pubovaginal Suspension For Stress Incontinence," J. Urology, 138:3, 568-570 (1987).				
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Examiner Signature		Date Considered
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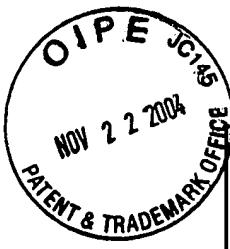
Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
				Application Number	10/642397
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	7	of	7	Attorney Docket Number	MIY-P02-024

	C27	Stamey, T.A., "Endoscopic Suspension of the Vesical Neck for Urinary Incontinence in Females," Annals of Surgery, 192:4, 465-471 (1980).	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		Application Number	10/642397
		Filing Date	August 14, 2003
		First Named Inventor	Michael S. H. Chu
		Art Unit	N/A
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission		Attorney Docket Number	MIY-P02-024

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Date	November 18, 2004

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